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March 13, 2009

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, room 1061
Rockville, MD 20852

Dear Dockets Staff:

Please enter the enclosed Citizens Petition into the Dockets Management system and forward it as appropriate within the Agency.

Please note that there is an addendum to the Petition, itself. The addendum comprises a draft of a suitable classification regulation for the Agency's use.

Respectfully submitted,



Arthur K. Yellin, MS, RPh
FDA (CDRH) retired

FDA-2009-P-0150-0001

CP

Citizen Petition Concerning Classification of Medical Gloves Used to Prepare and/or Administer
Chemotherapeutic Agents

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Action Requested

The undersigned submits this petition requesting separate classification of medical gloves that are labeled and intended for use in preparing and administering chemotherapeutic drugs. This petition includes a draft classification regulation for consideration by the Center for Devices and Radiological Health. This draft was written while the petitioner was an FDA employee working with the medical glove industry.

Statement of Grounds

1 - Medical gloves that are labeled and intended for use in preparing and administering chemotherapeutic drugs are currently classified as "patient examination" gloves under 21 CFR 880.6250. This device classification regulation defines "patient examination" gloves as:

"A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner."

Medical gloves that are labeled and intended for use in preparing and administering chemotherapeutic drugs have a completely different intended use than patient examination gloves. In fact, they are intended for the protection of the wearer from the harmful effects of these drugs, many of which are extremely caustic and/or carcinogenic.

2 - Medical gloves that are labeled and intended for use in preparing and administering chemotherapeutic drugs are de facto subject to conformance to an ASTM standard, ASTM D6978-05, as well as the standards to which patient examination gloves are subject.

3 - Both the CDRH Office of Compliance and medical glove industry representatives have indicated that separate classification of medical gloves that are labeled and intended for use in preparing and administering chemotherapeutic drugs would be beneficial. Separate classification would result in generation of a separate product code and would enable the Office of Compliance to easily identify the manufacturers of these gloves.

Environmental Impact

No environmental impact is anticipated promulgation of this classification regulation. I am requesting categorical exclusion from the requirement for an environmental impact assessment under 21 CFR 10.30(C)(A).

Economic Impact


The actions requested by this petition will have any significant economic impact on any industry regulated by the Food and Drug Administration (FDA). FDA/CDRH would need to change the product codes assigned to those medical gloves that are labeled and intended for use in preparing and administering chemotherapeutic drugs that have already been cleared through the Premarket Notification process. However, the number of such submissions is not very great.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature)  MS, RPh

(Name of petitioner) Arthur K. Yellin

(Mailing address) 

Enclosure:

Draft proposed Classification Regulation

Preamble

Medical gloves need to be suitable for their intended use. Through the years, medical gloves have evolved to reflect different, specialized, intended uses, with each type having different characteristics. For example, gloves intended for orthopedic procedures are thicker, ob/gyn gloves are longer, dental gloves may be flavored, and gloves intended for the preparation and handling of hazardous materials such as chemotherapeutic agents will have chemical permeation resistance characteristics. While the first three are somewhat specialized, they are still intended for use as patient examination gloves. The latter are not.

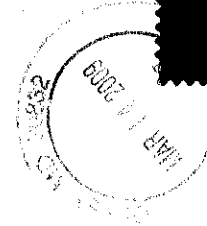
Over the years, a number of patient examination glove 510(k)s incorporating chemotherapeutic use claims, have been found substantially equivalent provided that they maintain their identity as "patient examination" gloves. CDRH has determined that these gloves require specialized labeling, based on use specific labeling, in order to assure their safe and effective use.

However, it is clear that gloves specifically intended for use in the preparation and handling of chemotherapeutic agents are not ordinary patient examination gloves. Therefore, CDRH is proposing to classify medical gloves intended for use in the preparation and handling of chemotherapeutic agents separately from patient examination gloves.

Proposed Reclassification Regulation

21 CFR 880.6255 – Medical glove intended for use in the preparation and handling of chemotherapeutic agents.

- (a) *Identification.* A medical glove intended for use in the preparation and handling of chemotherapeutic agents is a disposable device intended for medical purposes that is worn on the hand or finger to prevent exposure of the wearer to hazardous materials including chemotherapeutic agents.
- (b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Medical Gloves Intended for Handling Chemotherapeutic Agents; Guidance for Industry and FDA." In addition, these gloves are subject to special labeling requirements:
 - (1) Natural rubber latex medical gloves intended for use in the preparation and handling of chemotherapeutic agents shall bear the caution statement as required in Sec. 801.437(d).
 - (2) All medical gloves intended for use in the preparation and handling of chemotherapeutic agents shall be tested for permeation and penetration resistance with at least two chemotherapeutic agents and shall be labeled to indicate which agents were used.



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